MAR 27 2000

K000393

XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Alan A. Creamer, President, 9885 Mesa Ridge Rim, San Diego, CA 92121

I. Classification: Class II.

II. Common or usual name: dental curing light

III. Proprietary Name: Nova Cordless™

IV. Registration No.: In process

V. Classification Name: Tooth Shade Resin (accessory) EBF; and Activator, Ultraviolet, for Polymerization, EBZ, both Class II.

VI. Performance standards: None established (as a medical device) under section 514.

VII. Description: The Nova Cordless battery-operated hand-held light is cordless curing light using Light Emitting Diodes. No filters are required to block out harmful and unnecessary rays. The light produced by these diodes is specifically in the optimum curing range of 430 to 500 nanometers.

VIII. Labels and Labeling: Labels and Instructions for Use are provided. Competitive labels and labeling are provided and the products are compared.

IX. Indications for Use: source of illumination for curing dental restorative materials.

X. Substantial Equivalence: The Nova Cordless™ Nova Cordless™ is substantially equivalent to Dentsply's Spectrum Curing Light cleared under K-951425. It is also substantially eqauivalent to Sunrise Technology's Sunrise Curing Lamp cleared under K962192; and the ADT 1000 Plasma Arc Curing light cleared under K952333. Nova Cordless™ is also equivalent to several low power lasers such as the Arago, cleared in K971118 by Premier Laser, Inc. and to the 3M Aurora system cleared under K972355 and others.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

Mr. Alan A. Creamer
President
Nova/Da Vinci Systems Inc.
9885 Mesa Rim, Suite 127
San Diego, California 92121

Re: K000393
Trade Name: Nova Cordless™ Curing Light
Regulatory Class: II
Product Code: EBZ
Dated: February 4, 2000
Received: February 7, 2000

Dear Mr. Creamer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000393

IX. Indications for Use: [Separate Page]

510(k) Number: NA K000393

Device Name: Nova Cordless™ Curing Light

This device is intended for use as:

1. Source of illumination for curing dental restorative materials,

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000393